6560-50

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2011-0754; FRL- 9525-5]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request

AGENCY: Environmental Protection Agency

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to extend the current approval for the Information Collection Request (ICR) entitled "Pesticide Data Call-In Program" and identified as EPA ICR No. 2288.02 and OMB Control No. 2070–0174. The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost, and is available in the docket for additional public review and comment.

DATES: Additional comments may be submitted on or before [Insert date <u>30 DAYS AFTER</u> PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OPP–2011-0754, to (1) EPA online using http://www.regulations.gov (our preferred method), by mail to the OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, and (2) OMB by mail to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Cameo Smoot, Field and External Affairs Division, 7506P, Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave., NW, Washington, DC 20460; telephone number: 703-305-5454; fax number: 703-308-5884; email address: smoot.cameo@epa.gov.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures under the PRA (44 U.S.C. 3501 *et seq.*), as prescribed in 5 CFR 1320.12. On October 12, 2012 (77 FR 62232), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). Given the nature of this request, EPA did not consider new public comments. As required by the PRA, EPA is hereby soliciting additional comments on this ICR, which should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2011-0754, which is available for online viewing at http://www.regulations.gov. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

Title: Pesticide Data Call-In Program.

ICR numbers: EPA ICR No. 2288.02, OMB Control No. 2070–0174.

ICR Status: EPA is requesting a short renewal of the currently approved ICR. The submitted ICR package is unchanged from that which is currently approved. This extension will provide additional time to allow EPA to finish restructuring the ICR and related improvements to the electronic forms and instructions, as well as to consult with stakeholders and OMB on those changes and the corresponding adjustments to the burden estimates. This extension is necessary because the ICR covers ongoing activities that are required to support the statutorily mandated pesticide reviews.

The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost. The existing approval is scheduled to expire on November 30,

2012. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the <u>Federal Register</u> when approved, are listed in 40 CFR part 9, are displayed either by publication in the <u>Federal Register</u> or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), every pesticide product must be registered with EPA. An applicant for registration must supply data to demonstrate that the pesticide product will not cause "unreasonable adverse effects" on humans or to the environment. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA must determine, from data supplied by the applicant or registrant, that the level of pesticide residues in food and feed will be safe for human consumption, defined as "a reasonable certainty that no harm" will result from exposures to pesticide residues. Although data is provided with the initial applications, the Agency issues Data Call-Ins (DCIs) when it has determined that more information is necessary to make the necessary decision pursuant to the mandates in FIFRA and FFDCA.

The programs represented in this proposed ICR renewal and consolidation share a common statutory authority, section 3(c)(2)(B) of FIFRA, which authorizes EPA to require pesticide registrants to generate and submit data to the Agency, when such data are needed to maintain an existing registration of a pesticide. EPA's determination that additional data are needed can occur for various reasons, with the following four reasons being the most common:

- 1. Reregistration program. Section 4 of FIFRA requires EPA to re-assess the health and safety data for all pesticide active ingredients registered before November 1, 1984, to "reregister" them, i.e., determine whether these "older" pesticides meet the criteria for registration that would be expected of a pesticide being registered today for the first time. FIFRA section 4 directs EPA to use FIFRA section 3(c)(2)(B) authority to obtain the required data. Although the Reregistration Eligibility Decisions are complete, the Agency may still need to issue DCIs to close out the program.
- 2. Registration review program. Section 3(g) of FIFRA contains provisions to help achieve the goal of reviewing each pesticide every 15 years to assure that the pesticide continues to pose no risk of unreasonable adverse effects on human health or the environment. FIFRA section 3(g) instructs EPA to use the FIFRA section 3(c)(2)(B) authority to obtain the required data.
- 3. Special review program. Though rare, EPA may conduct a Special Review if EPA believes that a pesticide poses risks of unreasonable adverse effects on human health or the environment. Section 3(c)(2)(B) of FIFRA provides a means of obtaining any needed data.
- 4. Anticipated residue/percent crop treated information. Under section 408 of FFDCA, before a pesticide may be used on food or feed crops, the Agency must establish a tolerance for the pesticide residues on that crop or established an exemption from the requirement to have a tolerance. Section 408(b)(2)(E) and (F) of FFDCA authorize the use of anticipated or actual residue (ARs) data and percent crop treated (PCT) data to establish, modify, maintain, or revoke a tolerance for a pesticide. The FFDCA requires that if AR data are used, data must be reviewed five years after a tolerance is initially established. If PCT data are used, the FFDCA affords EPA the discretion to obtain additional data if any or all of several conditions are met.

Page 5 of 5

The Agency issues DCIs when it has determined that more information is necessary to

make a decision about pesticides pursuant to the mandates in FIFRA and FFDCA. Agency

decisions requiring additional data are based on the data requirements set forth in 40 CFR parts

150 through 180, with the majority of the data requirements captured in 40 CFR parts 158 and

161.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of

information is estimated to range from 59 to 13,636 hours per response, depending on the review

program and type of DCI issued. Burden is defined in 5 CFR 1320.3(b). The ICR provides a

detailed explanation of this estimate, which is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by this ICR include pesticide

registrants, which may be identified by the North American Industrial Classification System

(NAICS) code 32532, pesticide and other agricultural chemical manufacturing.

Frequency of Collection: On Occasion

Estimated No. of Potential Respondents: 1643.

Estimated No. of Total Annual Responses: 184.

Estimated Total Annual Burden on Respondents: 262,301 hours.

Estimated Total Annual Costs: \$12,506,726.

Changes in the Estimates: The total estimated burden for this ICR is unchanged from that

currently approved by OMB.

John Moses, Director, Collection Strategies Division